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EXAMINER

FOX, DAVID T

ART UNIT

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/903,944
Filing Date: July 31, 1997
Appellant(s): CHOU ET AL.

Michael S. Greenfield
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 April 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 73-96, 100 and 112.

Claims 1-72, 97-99, 101-111 and 113-118 have been canceled.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 07 April 2004 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The enablement rejection of claims 73-96, 100 and 112 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

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The written description rejection of claims 73-75, 83 and 85 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

A substantially correct copy of appealed claims 84, 91 and 94-96 appears on pages A-2 and A-3 of the Appendix to the appellant's brief. The minor errors are as follows:

In claim 84, line 1, "in" should be replaced with ---is---.

In claim 91, line 1, "isopentyenyl" should be replaced with ---isopentenyl---.

In claim 91, line 2, "isopentynyl" should be replaced with ---isopentenyl---.

In claim 94, line 3, "APETLA1" should be replaced with ---APETALA1---, and "APETALA2" should be replaced with ---APETALA3---.

In claim 95, line 1, ---the expression of--- should be inserted after "wherein", and "encodes a protein that" should be deleted.

In claim 96, line 1, ---foreign--- should be inserted after "said".

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Oran, S.A. "Potato Disc Bioassay for Some Jordanian Medicinal Plants",
Pharmaceutical Biology, Vol. 37, No. 4, (1999), pages 296-299.

Caesar, A.J. "Pathogenicity of *Agrobacterium* Species from the Noxious Rangeland Weeds *Euphorbia esula* and *Centaurea repens*", Plant Disease, Vol. 78, No. 8, (1994), pages 796-800.

Slightom et al. "Isolation and identification of TL-DNA/plant junctions in *Convolvulus arvensis* transformed by *Agrobacterium rhizogenes* strain A4", The EMBO Journal, Vol. 4, No. 12, (1985), 3069-3077.

Sinkar et al. "*rolA* locus of the Ri plasmid directs developmental abnormalities in transgenic tobacco plants", Genes and Development, Vol. 2, No. 6, (1988), pages 688-697.

Sukhapinda et al. "Ri-plasmid as a helper for introducing vector DNA into alfalfa plants", Plant Molecular Biology, Vol. 8, (1987), pages 209-216.

Visser et al. "Efficient transformation of potato (*Solanum tuberosum* L.) using a binary vector in *Agrobacterium rhizogenes*", Theoretical and Applied Genetics, Vol. 78, No. 4, (1989), pages 594-600.

Ooms et al. "Genetic manipulation in cultivars of oilseed rape (*Brassica napus*) using *Agrobacterium*", Theoretical and Applied Genetics, Vol. 71, No. 2, (1985), pages 325-329.

Trulson et al. "Transformation of cucumber (*Cucumis sativus* L.) plants with *Agrobacterium rhizogenes*", Theoretical and Applied Genetics, Vol. 73 (1986), pages 11-15.

David et al. "Conservation of T-DNA in plants regenerated from hairy root cultures", Bio/Technology, Vol. 2, No. 1, (January 1984), pages 73-76.

Pythoud et al. "Increased virulence of *Agrobacterium rhizogenes* conferred by the *vir* region of pTiBo542: application to genetic engineering of poplar", Bio/Technology, Vol. 5, (December 1987), pages 1323-1327.

Rech et al. "*Agrobacterium rhizogenes* Mediated Transformation of the Wild Soybeans *Glycine canescens* and *G. clandestina*: Production of Transgenic Plants of *G. canescens*", Journal of Experimental Botany, Vol. 39, No. 206, (September 1988), pages 1275-1285.

Follansbee et al. "Transformation of *Euphorbia lathyris* by *Agrobacterium rhizogenes*", In Vitro, Vol. 31, No. 3, (1995), page 72A.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112, first paragraph: enablement

Claims 73-96, 100 and 112 on appeal stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to transgenic poinsettia plants produced by a method comprising utilizing particle bombardment of embryogenic callus, does not reasonably provide enablement for claims broadly drawn to transgenic poinsettia plants produced by any method including *Agrobacterium*-mediated transformation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for the production of whole, flowering poinsettia plants produced by particle bombardment of embryogenic callus. In contrast,

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the claims are broadly drawn to transgenic poinsettia plants produced by any method including the use of the natural gene transfer system of the pathogenic bacterium *Agrobacterium*. The use of either of two *Agrobacterium* species, namely *Agrobacterium tumefaciens* and *Agrobacterium rhizogenes*, is widely known in the plant transformation art as a relatively rapid method of plant transformation which generates a high frequency of transformants. (See also page 10 of the specification, line 37 through page 11, line 9, where *Agrobacterium*-mediated transformation is the only other transformation method contemplated by Appellant.) The claims are also broadly drawn to the production of transgenic plants from any poinsettia variety of any genetic makeup, and to the production of fertile plants.

The *Agrobacterium*-mediated transformation of the plant genus *Euphorbia*, particularly the *Euphorbia* species of poinsettia (*Euphorbia pulcherrima*), and the obtention of whole transformed plants is unpredictable, as evidenced by Follansbee et al, who were unable to recover whole *Euphorbia* plants following *Agrobacterium rhizogenes*-mediated transformation (see, e.g., page 72A, Abstract). This failure is in sharp contrast to the successful obtention of whole plants from a variety of taxonomically and genetically unrelated species including morning glory, tobacco, alfalfa, potato, rapeseed, cucumber, carrot, poplar, and soybean, following *Agrobacterium rhizogenes*-mediated transformation. See, e.g., Slightom et al, page 3069, Abstract; Sinkar et al, page 688, Abstract and page 695, column 2, top paragraph; Sukhapinda et al, page 209, Abstract; Visser et al, page 594, Abstract; Ooms et al, page 325, Abstract and page 327, Figure 1D; Trulson et al, page 11,

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Abstract; David et al, page 73, Abstract; Pythoud et al, page 1323, Abstract and second paragraph of column 2, page 1325, column 2, first full paragraph; Rech et al, page 1275, Abstract.

Furthermore, *Agrobacterium tumefaciens*-mediated transformation of poinsettia is unpredictable and unlikely, given the host range limitations of the bacterium and the failure of any workers to report successful transformation of poinsettia via *A. tumefaciens*. Oran teaches that plant extracts of another *Euphorbia* species were toxic to *Agrobacterium tumefaciens* (see, e.g., page 297, Table 1 and page 298, Table 2). Caesar teaches that there are few strains of *Agrobacterium tumefaciens* that successfully infect another *Euphorbia* species, wherein no strains were previously reported to be infective (see, e.g., page 797, column 3, bottom paragraph; page 798, top paragraph of column 1, first full and bottom paragraphs of column 2; page 799, Table 3).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of non-exemplified transformation methods including *Agrobacterium*-mediated transformation for their ability to produce whole, transformed, fertile poinsettia plants of any variety or genotype.

Appellant's Arguments and Examiner's Response

Appellant urges that the enablement rejection is improper, since the claims on appeal are all drawn to products and not processes of making products, wherein product claims are enabled if the specification teaches at least one method of making

the product. Appellant cites *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, (Fed. Cir. 2003), *The Johns Hopkins University v. CellPro, Inc.*, (Fed. Cir. 1998), and *Durel Corp. v. Osram Sylvania Inc.*, (Fed. Cir. 2001) to support his position. See page 3 of the Brief.

The Examiner maintains that the case law cited by Appellant involves different fact patterns than those of the instant invention, and that the cited case law actually supports the Examiner's position.

Appellant's arguments are predicated upon the position that the claimed products, i.e. transformed poinsettia plants, are identical regardless of the method of making them. However, this is not the case.

It is well known in the art that the use of *Agrobacterium*-based plant transformation vectors results in the integration into the plant nuclear genome of the T-DNA borders, which are 25 base pair long repeated sequences flanking either end of the foreign DNA of interest to be inserted into the plant. The T-DNA borders are part of the natural gene transfer system of the *Agrobacterium* organism, and they occur on the plasmid DNA which is used to transfer DNA of interest into the recipient plant host genome. In nature, the bacterial DNA between the T-DNA borders comprises tumor genes which cause a pathogenic tumor response in plants which have been infected by *Agrobacterium*, due to the integration of the bacterial tumor genes into the plant genome. During *Agrobacterium*-mediated transformation, the piece of the bacterial plasmid including the tumor genes and the flanking T-DNA borders are all integrated into the plant nuclear genome. Genetic engineers have been able to delete part or all of the bacterial tumor genes, and insert in their place a gene of interest conferring to a

crop plant a trait of interest such as disease resistance, e.g. a viral gene encoding a viral protein which immunizes a plant against subsequent attack by the virus when the plant contains the viral gene alone. The use of an *Agrobacterium*-based vector comprising the T-DNA borders flanking a foreign disease resistance gene will result in the production of a transformed plant which has the foreign disease resistance gene, *flanked by the T-DNA borders*, integrated into its nuclear DNA genome.

In contrast, particle bombardment-mediated transformation involves the use of microscopic particles which are coated with DNA molecules containing a gene of interest, wherein the microparticles are physically propelled into plant tissue with great force. It is the propulsion of the particles that results in the integration into the plant genome of the DNA covering them. No T-DNA borders are required in the DNA to be propelled. Thus, poinsettia plants which were produced by particle bombardment would not contain the 25 base pair long T-DNA borders. The Patent and Trademark Office Board of Appeals has previously decided, in an unpublished decision, that the presence of the 25 base pair long T-DNA borders rendered a transformed plant containing them patentably distinct from a transformed plant not containing them. This supports the Examiner's position that the instant claims read on two different products, while the specification only enables a method of making one of the two products.

In *Amgen Inc. v. Hoescht Marion Roussel*, the claims were drawn to the proteinaceous product of erythropoietin and methods of making the product via the transformation of various cell types with DNA encoding the erythropoietin (see, e.g., 65 USPQ2d 1385 at pages 1390-1391). In contrast to the instant situation, the defendant

in *Amgen* never asserted that "the patentability of the product claims in suit depended upon the process by which those products are obtained" (*Id.*, page 1395, bottom two paragraphs). Furthermore, this point was never raised during the prosecution of the original patent (*Id.*)

In addition, the Court in *Amgen* framed the enablement issue in that case as follows: was the patent specification enabling for all methods of producing a single protein encoded by a single nucleotide sequence, namely human erythropoietin, wherein said methods included the transformation and culture of various types of vertebrate cells, which transformation methods required different regulatory sequences functional in each type of vertebrate cell, and which culture methods required different culture media and culture conditions? In *Amgen*, the Court considered evidence that demonstrated that the use of regulatory elements specific for different kinds of host vertebrate cells, and the use of culture methods specific for different kinds of host vertebrate cells, were within the skill level of the ordinary artisan. *Ibid.*, paragraph bridging pages 1400 and 1401, and page 1401, bottom paragraph. However, Appellant is reminded that the character of the *claimed product* in *Amgen*, namely the single protein of human erythropoietin, was independent of the process used to make it. In the instant case, the character of the product of a transformed poinsettia plant is materially influenced by the method of making it, i.e. *Agrobacterium*-mediated transformation or particle bombardment-mediated transformation, due to the presence of the T-DNA borders in the plant genome when the former technique is used.

In *The Johns Hopkins University v. CellPro Inc.*, the claims were drawn to a pure suspension of immature human blood cells, i.e. stem cells, and to monoclonal antibodies which bind to an antigen only found on immature but not mature human blood cells, namely the My-10 antigen, wherein said monoclonal antibodies may be used to separate immature blood cells in a mixed solution of immature and mature blood cells. See 47 USPQ2d 1705 at pages 1707-1708, top paragraph. The defendant failed to provide convincing evidence that the claims were not enabled, since the patent specification was not deemed deficient even by the infringers, and since the alleged experts utilized by the defendant to demonstrate lack of success did not in fact utilize the methods taught in the specification, or were inexperienced undergraduate students not considered artisans of even ordinary skill (*Id.*, page 1711, second full paragraph and bottom paragraph; page 1718, bottom three paragraphs). Furthermore, the Court concluded that the defendant failed to raise "a genuine factual dispute concerning the enablement of the claims" (*Id.*, page 1719, second full paragraph).

In fact, *Johns Hopkins* supports the Examiner's position in its teaching that the defendant "can carry its burden only by showing that all of the disclosed alternative modes are insufficient to enable the claims" (*Id.*, page 1719, first full paragraph). In the instant case, the Examiner has conclusively demonstrated that the alternative mode of producing the claimed product, namely *Agrobacterium*-mediated transformation, is indeed insufficiently enabled.

In *Durel Corp. v. Osram Sylvania Inc.*, the claims were drawn to encapsulated electroluminescent phosphor particles which contained metal oxide coatings (see 59

USPQ2d 1238 at page 1239, bottom two paragraphs). At the outset, it is noted that *Durel* involved the relatively predictable physical and electronic arts, while the instant claims involve the relatively unpredictable physiological and chemical arts. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), which teaches the need for "a reasonable correlation" between the scope of the claims and "the scope of enablement provided by the specification", wherein "the scope of enablement obviously varies conversely with the degree of unpredictability of the factors involved" in "cases involving unpredictable factors, such as most chemical reactions and physiological activities".

The Court in *Durel* determined that the defendant's arguments regarding enablement, based upon the alleged failure of various precursors to produce a single product, namely the claimed metal oxide coating, were immaterial, as long as at least one of the precursors was sufficient to enable the production of the single product, i.e. the resultant metal oxide (*Id.*, page 1244, penultimate paragraph). However, the Court raised the issue of the enablement of various types of metal oxide products, and stated that this issue was not settled and was suitable for remand (*Id.*, paragraph bridging pages 1244 and 1245). In other words, the Court did not decide that *the various types of products* encompassed by the claims were all enabled. Thus, *Durel* supports the Examiner's position in the instant case, since the instant claims are broadly drawn to different types of products rather than to a single product.

35 USC 112, first paragraph: written description

Claims 73-75, 83 and 85 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any transgenic poinsettia plant which contains any heterologous coding sequence conferring any trait. The heterologous coding sequence, or "foreign gene", is not characterized with respect to source, i.e. bacterial, fungal, viral, animal or plant source, let alone a particular species within each of the above categories. No guidance has been provided for the characterization of a multitude of coding sequences encoding a multitude of proteinaceous or non-proteinaceous products conferring a multitude of traits. Only specific coding sequences conferring disease or insect resistance, herbicide resistance, modified plant habit, ethylene resistance, antibiotic resistance, early flowering, and delayed senescence were provided (see page 2 of the specification, lines 5-6, 14-15 and 27-36; page 3, lines 12-20; page 5, lines 29-32; page 6, lines 6-9 and 24-26; page 12, lines 17-20; page 28, lines 25-28; page 29, lines 21-22 and 28-29; page 30, lines 31-33; page 38, lines 35-38; page 39, lines 1-2 and 5-6; page 40, lines 3-6, 13-15 and 27-29; page 41, lines 8-11; and claims 76, 78 and 95).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

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precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, that "structural features common to members of the genus" should be recited, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Appellant's Arguments and Examiner's Response

Appellant urges that the written description rejection is improper, given the clarification of *Eli Lilly by Enzo Biochem, Inc., v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002), regarding "the written description required for new and previously unknown biological materials" (see page 4 of the Brief, bottom paragraph). Appellant further urges that *Amgen Inc. v. Hoescht Marion Roussel* cited above supports his position that the claimed invention is supported by an adequate written description, since it is not drawn to "new or unknown biological materials that the ordinary skilled artisan would easily misapprehend" (Brief, page 5, bottom paragraph).

The Examiner maintains that the case law cited above involves different fact patterns than the instant case, and that the cited case law supports the Examiner's position. Furthermore, the Examiner respectfully disagrees with Appellant's characterization of the claimed invention as it relates to the above-cited cases.

Appellant urges that the instantly claimed transformed poinsettia plants containing a variety of unspecified foreign genes are not "new or unknown biological materials that the ordinary skilled artisan would misapprehend", since one of ordinary skill in the art would easily recognize said plants as merely containing "non-poinsettia genes" (Brief, paragraph bridging pages 5 and 6). However, the broadly claimed genus of transformed poinsettia plants, containing a broadly claimed genus of unspecified foreign genes, is clearly drawn to new or unknown biological materials, as taught by the cases cited above.

The rejected claims encompass transgenic poinsettia plants comprising any "foreign gene" (see, e.g., claim 73). The foreign gene is not characterized with respect to any sequence, any encoded protein, any function of the encoded protein, or any common structural features (including sequence domains or conserved sequences) shared by the genus of any foreign protein or any foreign gene encoding it. The specification recites the following functions as examples of those encoded by the foreign gene: flower color, fragrance, and superior post harvest and shipping qualities (see, e.g., page 2, lines 31-36). However, the specification does not characterize or describe any isolated gene from any organism encoding any protein which would confer the above traits. Furthermore, the specification admits that poinsettias are fragrance-free, and no one has identified, isolated, characterized or described any gene encoding any protein which would confer any particular fragrance, such as rose-like or lilac-like fragrance, thereto (see, e.g., page 39, lines 1-4). Finally, the specification contemplates that the foreign gene may encode a multitude of non-proteinaceous products, such as antisense RNA, ribozymes or external guide sequences (see, e.g., page 9, lines 7-26; page 13, line 35 through page 15, line 2).

In addition, the specification does not describe any isolated gene encoding any isolated protein conferring blue, black, yellow or orange flower color to poinsettias. Moreover, "foreign gene" could encompass those genes encoding proteins which confer increased tissue culturability, frost tolerance, non-green leaf color, or animal defense via thorn production, among countless other non-exemplified genes encoding a multitude of non-exemplified proteins conferring a multitude of non-exemplified functions, none of

which have been described in the instant specification. Thus, the genus of "foreign gene" indeed encompasses "new or unknown biological materials that the ordinary skilled artisan would easily misapprehend". Therefore, the genus of transformed poinsettia plants containing any uncharacterized foreign gene is inadequately described by the instant specification. See the Written Description Guidelines cited above.

Furthermore, *Enzo* does not support Appellant's position. In *Enzo*, the claims were drawn to DNA fragments which are diagnostic for the presence of the bacterium *Neisseria gonorrhoeae*, wherein said DNA fragments were defined on the basis of their function to identify *Neisseria gonorrhoeae* DNA by preferentially hybridizing thereto, wherein three such DNA fragments from *N. gonorrhoeae* were actually deposited, and wherein the claims also encompassed any mutant or subsequence thereof from any source (see, e.g., pages 2-5 of the Opinion published by the Federal Circuit.) The Court in *Enzo* accepted the criteria set forth in the Written Description Guidelines cited above, namely that "the written description requirement *can be* [emphasis added] met" by the mere disclosure of "functional characteristics when coupled with a known or disclosed correlation between function and structure" (*Id.* Page 9, citing Guidelines, 66 Fed. Reg. at 1106).

However, the Court in *Enzo* did not actually determine that the disclosure of three particular DNA fragments was sufficient to adequately describe the claimed genus. Instead, the Court determined that the prior granting of summary judgment was in error, and that the case should be remanded to the District Court to decide the question (see, e.g., pages 12-14 of the Decision). It is noteworthy that the claims in *Enzo* were limited

to a genus comprising *N. gonorrhoeae* sequences, which genus was defined by the function of preferentially hybridizing to *N. gonorrhoeae*. Even with the relative narrowness of the claims and the positive recitation of a function, the claims were not automatically deemed to be supported by an adequate written description.

In the instant case, the rejected claims do not recite *any source*, and so encompass sequences from viruses, bacteria, fungi, plants and animals. The instant claims do not recite any structure, i.e. sequence, which is common to the broadly claimed genus and which is correlated with the function of that particular genus, as required by *Lilly* and *Enzo*. Furthermore, the instant claims do not recite *any function* of the foreign gene or the protein encoded by it. Thus, there is no function with which to correlate structure. In addition, there is no common structure to protein-encoding genes, antisense RNA –encoding genes, ribozyme-encoding genes, or external guide sequence-encoding genes.

Even for the disclosed species of insect resistance, modified flowering or plant growth habit, or disease resistance, there is no demonstration of correlation of conserved structure (i.e. conserved protein sequence or conserved DNA sequence) either between these species or across the broadly claimed genus of any transgene conferring any trait. See MPEP 2163. It is highly unlikely that the Court in *Enzo* would find that the instant claims were supported by an adequate written description, in view of their treatment of the much narrower claims in that case.

In *Amgen* cited above, the issue of written description was applied to claims drawn to any type of vertebrate cell which comprised a single nucleic acid sequence

encoding a single protein, namely human erythropoietin. It was ultimately decided that claims drawn to such a genus were in fact adequately described, because the narrowly claimed DNA genus limited to a single gene encoding human erythropoietin was adequately described, and because the artisan of ordinary skill would easily recognize different types of vertebrate cells (65 USPQ2d 1385 at page 1398, penultimate paragraph; page 1399, penultimate paragraph). However, the instant fact pattern is much different—only a single type of plant species as the recipient for the foreign DNA is claimed, namely poinsettia. Furthermore, the foreign DNA to be introduced into the recipient plant species is completely unspecified and uncharacterized, and therefore inadequately described. The genus of foreign DNA encompasses a multitude of non-exemplified, unspecified transgenes encoding a multitude of unspecified and unrelated products.

It is noted that the Examiner proposed a series of Examiner's amendments which would have placed the application in condition for allowance. See the attachement to the Advisory Action of 30 January 2004. Unfortunately, Appellant declined these amendments.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



David T. Fox
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July 7, 2004

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